

**REMARKS**

This Amendment is filed in response to the Advisory Action dated February 18, 2003, and the Final Rejection dated December 4, 2002. Applicants understand that the amendment submitted on February 4, 2003, was not entered. Therefore, the amendment herein is submitted for entry in response to the Final Rejection. All objections and rejections are respectfully traversed. Examiner states that claims 1, 2, 4-8, 10, 11, 19, 22, 26, 35-38, 43, 45-49, 56, 79-85, 91-94, and 97 are currently pending in the Application. Applicants have cancelled claims 11, 19, 38, and 43. Applicants respectfully request that claims 41 and 87-89 be reconsidered for inclusion, and arguments to that effect are included herein. Applicants have herein amended claims 7, 22, 35, 45, 49, 81, and 94 to correct typographical errors, respond to Examiner's objections, and put those claims in condition for allowance. Applicants have added claim 98.

At paragraph 1 of the Official Action, Examiner states that the proposed drawing correction is disapproved. However in a subsequent phone conversation on January 17, 2003, Examiner states that reference numbers 341, 350, and 321 are adequately illustrated in FIGs. 1 and 2B, and are therefore not new matter. Applicants understand that the objection of paragraph 1 has been withdrawn.

At paragraph 2 of the Official Action, Examiner has accepted the substitute specification.

At paragraph 3 of the Official Action, Examiner has objected to the amendment of 8/28/02 under 35 USC § 132 because Examiner states that the amendment contains new matter. Applicants have amended claims 7 and 45 according to Examiner's requirements.

At paragraphs 4-5, Examiner states that claims 7, 45, and 81 are rejected under 35 USC § 112, first paragraph, a containing subject matter that was not discussed in the specification. Applicants have amended claims 7, 45 and 81 according to Examiner's requirements. In particular, in claims 45 and 81, the term "cellulose" was replaced by the word "cotton". Applicants, however, disagree with Examiner that the introduction of the term "cellulose" presents new matter in the specification considering that the information provided in the specification more than adequately supports the use of this term in these claims.

At paragraphs 6-8, Examiner states the claim 35 is rejected under 35 USC § 112, second paragraph, as failing to particularly point out and distinctly claim the invention. Applicants have amended claim 35 according to Examiner's requirements.

At paragraph 9, Examiner states that claim 19 is rejected under 35 USC § 101 because there exists a positive recitation of a human and/or human anatomy as part of the claimed invention. Applicant herein cancels claim 19.

At paragraphs 10-16, Examiner states that claims 1, 2, 4-8, 11, 26, 35-38, and 43 are rejected under 35 USC § 102(e) as being anticipated by Holland et al., United States Patent # 5,957,904, issued 9/28/1999 (Holland). Applicants herein cancel claims 38 and 43. Applicants do not believe that the female collection device of Holland anticipates Applicants' invention. Applicants herein recite critical differences between Holland and the present invention as claimed.

At paragraphs 17-25, Examiner states that claims 1, 45, 56, 79, 82-85, 91-94, and 97 are rejected under 35 USC § 103(a) as being unpatentable over Anderson, United States Patent # 6,068,618, issued 5/30/2000, in view of Holland. Applicants do not believe that Anderson in view of Holland render Applicants' invention obvious, the reasons for which are spelled out herein.

At paragraph 26, Examiner restates that the amendment of 8/28/02 is objected to under 35 USC § 132. See above.

At paragraph 27, Examiner states that added claim 95 is relabeled to claim 97.

At paragraph 28, Examiner states that claim 22, if rewritten in independent form including all the limitations of the base claim and any intervening claims (claims 1 and 4), is allowable. Applicants have rewritten claim 22 in allowable form and have added claim 98 which is the previous version of claim 22.

At paragraphs 29-30, Examiner states that Applicants' arguments with respect to the election of species have been fully considered but are not persuasive. Applicants herein resubmit the arguments for claims 41 and 87-89 in light of the phone conversation of January 17, 2003 (described previously).

At paragraph 31, Examiner states that the arguments of the previous amendment are moot in view of new grounds for rejection.

**Election of species claims**

Claim 41: Examiner states that the straps connected to the means for storage are not shown in FIGs. 1, 2A, and 2B. Applicants respectfully point out that the attachment straps 321 are shown but not labeled in FIG. 2B. Applicants have submitted substitute drawing FIG. 2B for Examiner's approval showing the reference numeral 321 identifying Applicants' attachment straps. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 41.

Claim 87: Examiner states that the absorbent material in the means for storage is drawn to a non-elected species. In substitute drawing FIG. 1, Applicants have labeled absorption/storage elements 350. These elements are described throughout the specification as being constructed of absorbent material. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 87.

Claim 88: Examiner states that the means for distributing urine is drawn to a non-elected species. In substitute drawing FIG. 1, Applicants have labeled wicking conduits 341. These elements are described throughout the specification as being used to distribute urine throughout the storage container. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 88.

Claim 89: Examiner states that the means for attaching the storage container is drawn to a non-elected species. In substitute drawing FIG. 2B, Applicants have labeled attachment straps 321. These elements are described throughout the specification as being used to attach the storage container to the leg of the human male. Applicants respectfully request Examiner's reconsideration of the withdrawal of claim 89.

**35 U.S.C. § 102 and 103 rejections**

The present invention, as set forth in representative claim 1, comprises in part:

1. (previously amended) A system for collecting, conveying, and storing urine discharged from a penis of a human male comprising
  - means for collection of said urine from said human male comprising proximal and distal ends and outer and inner surfaces;
  - means for storage of said urine before disposal of said urine comprising proximal and distal ends and outer and inner surfaces;

means for conveying said urine from said means for collection of said urine to said means for storage of said urine comprising proximal and distal ends and outer and inner surfaces; and

means for wicking said urine away from the penis wherein said means for wicking moves said urine counter-gravitationally and gravitationally away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage.

Holland discloses a collection device that relies on gravity to move urine from the collection site to a wick that is located “substantially along the bottom edge 17 of the receptacle 11 so that a **gravity effect** of urine in the reservoir also works on the wick to cause urine to be absorbed by the wick 30 **prior to** draining into the collection bag 31” (Col. 4, lines 38-42). Holland discloses a receptacle within which “is contained a cone-shaped reservoir which has a wicking system which drains through an orifice into a tubing. . . . The tubing is directed to a **collection bag intended to be located below the receptacle**. The wick feeds urine **under gravity** from the reservoir into the tube and down into the collection bag” (Col. 1, lines 60-67). Holland, which doesn’t even require a wick (Col. 7, lines 49-58), accommodates position-dependence by locating, in an alternate embodiment, two orifices 60 and 61 on opposite sides of the device so that gravity can carry the urine away from the user no matter on which side the user lays (FIG. 10).

Applicants claim that the “*means for wicking moves said urine counter-gravitationally and gravitationally away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage*”. Applicants claim a means for wicking that (1) begins at the site of collection and (2) extends throughout the system, including into the claimed means for storage. Holland’s wicking system starts **after** gravity has moved urine away from the collection site and ends **before** urine enters a collection bag which, although pictured and mentioned in the description, is not fully described nor claimed. Nowhere does Holland anticipate a device that moves urine through an entire system that includes collection, conveyance **and** storage, from collection site to storage device, omni-directionally, regardless of the position of the wearer.

The wick of Holland, at most, extends into the tubing, but certainly not into a collection bag. Applicants’ “*means for storage*”, that is part of the urine path described in

a “*means for wicking . . . through said means for collection and said means for conveying, and deposits said urine in said means for storage*”, that extends from the interior of the collector to the interior of the storage means, enables the Applicants’ invention to be capable of inducing urine flow in either counter-gravitational or gravitational direction throughout the urine pathway, from point of collection to point of urine storage.

In view of the absence from any cited patent of Applicants’ claimed “*means for wicking moves said urine counter-gravitationally and gravitationally away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage*”, Applicants respectfully urge that the Holland patent is legally insufficient to render the presently claimed invention anticipated under 35 U.S.C. § 102.

Anderson discloses a male catheter that does not involve wicking. Anderson discloses a design of a urine collection and storage system for human males that features a specific configuration of a male external catheter: one that is constructed of a tubular sheath formed from a single layer of elastic material. The thickness of the sheath varies, being thicker at the proximal end when fitted over the penis, so that the thicker region is able to provide a uniform, radially-compressive force on the penis. Anderson assumes that gravity drives the flow of urine from collector to storage bag, and does not teach nor suggest the use of a wicking means to move emitted urine from the collection device to storage.

Neither Holland nor Anderson teach or suggest (1) a device that transports urine counter-gravitationally from the site of collection, nor (2) a device that transports urine counter-gravitationally into the storage device. The combination of Holland and Anderson could form a collector that contains a wick lining the surface of its outer sheath, should one design such a system using impermissible hindsight. However, neither was such a system taught nor suggested by either invention, nor does that impermissible invention teach wicking away from the collection site nor wicking into a storage device.

What is missing from the combination of Anderson and Holland, but is clearly claimed by Applicants’, is the ability of the wicking capability to induce urine to flow

from the collection site in counter-gravitational direction into the storage device, thereby enabling passage of urine over points that are higher than the source from the time the urine exits the user's body until the time the urine enters the interior of the storage bag.

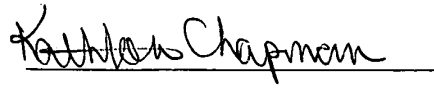
With respect to Anderson's radial compression tube (30), Anderson clearly describes only a single layer sheath in which the compression band is a physical extension of the collecting tube itself. Applicants claim (claim 8) "***means for collection comprises means for wicking the urine away from the penis; thin-wall hollow conduction tube having proximal and distal ends and a cavity sufficiently large to surround the penis; and compression tube having proximal and distal ends and sufficient size to be disposed around and provide radial compression contact upon the penis at said proximal end of said conduction tube, wherein said means for wicking is disposed within said conduction tube.***"

In view of the absence from any cited patent of Applicant's claimed "***means for wicking moves said urine counter-gravitationally and gravitationally away from the penis through said means for collection and said means for conveying, and deposits said urine in said means for storage***", Applicants respectfully urge that neither Anderson nor Holland, singly or in combination, is legally insufficient to render the presently claimed invention anticipated under 35 U.S.C. § 103.

All independent claims are believed to be in condition for allowance. All dependent claims are believed to depend upon allowable independent claims, and therefore in condition for allowance. Should it be necessary, Applicants reserve the right to swear behind the invention of Holland.

Favorable action is respectfully solicited.

Respectfully submitted,

A handwritten signature in cursive script, reading "Kathleen Chapman", is written over a horizontal line.

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